DEPARTMENT OF HEALTH & HUMAN SERVICES



Food and Drug Administration Rockville MD 20857

The Honorable Rush Holt House of Representatives Washington, D.C. 20515-3012

Dear Mr. Holt:

Thank you for your letter of July 22, 1999, on behalf of your constituent, Mr. Priya Narasimhan of Flemington, New Jersey, concerning actions by the Food and Drug Administration (FDA or the Agency) in regard to labeling of foods treated with ionizing radiation.

The 1997 FDA Modernization Act (PL 105-115) states that "[n]o provision . . . shall be construed to require on the label or labeling of a food a separate radiation disclosure statement that is more prominent than the declaration of ingredients . . ." FDA published a final rule implementing this provision of the law in the Federal Register of August 17, 1998. A copy of this regulation, along with the labeling requirements for food treated with ionizing radiation, Title 21 Code of Federal Regulations, § 179, is enclosed for your information.

In addition, the Statement of Managers accompanying the FDA Modernization Act directed FDA to publish for public comment further proposed changes to the Agency's current labeling regulations. The managers stated their intention that any required labeling be of a type and character such that it would not be perceived to be a warning or give rise to inappropriate consumer anxiety. On February 17, 1999, FDA published an Advance Notice of Proposed Rulemaking (ANPR) in the Federal Register soliciting public comment on whether additional revisions to the current irradiation labeling requirements are needed and, if so, what form such revisions might take. The deadline for comments in response to the ANPR was extended to July 19, 1999.

We have forwarded your correspondence to the Docket for inclusion in the record. FDA's final approach to

9811-1038

C4749/ANS

Page 2 - The Honorable Rush Holt

labeling of irradiated foods will take into account all of the data and information received.

Because your constituent may be concerned about irradiation labeling for meat and poultry, you may also wish to contact the United States Department of Agriculture (USDA) for information. (USDA has primary regulatory authority over meat and poultry products, including the labeling of such products.)

We have also enclosed some general background on the issue of irradiation. We trust this information responds to your concerns. If you have further questions about this or any other matter, please do not hesitate to contact us again.

Sincerely,

for Melinda K. Plaisier

Interim Associate Commissioner for Legislation

Enclosures

cc: Dockets Management Branch

(98N-1038)

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Congress of the United States

July 22, 1999

Committee on Education and the Workforce

Committee on the Budget Social Security Task Force

Committee on Resources

Member

Congressional Arts Caucus
Congressional Working Group on Children
Congressional Fire Services Caucus
Sustainable Development Caucus
Caucus Crime and Drugs Task Force

Ms. Jane Kerby Food and Drug Administration 5600 Fisher Lane Rockville, MD 20857

Dear Ms. Kerby:

I am writing in regards to Docket #98-1038, "Irradiation in the production, processing and handling of food."

As a Member of Congress and as a consumer I oppose the idea of selling irradiated foods without proper labeling. This is not only inappropriate and misleading, but it also poses a threat to the credibility to the FDA. Many families rely upon the nutritional information on the packaging to make informed decisions.

Your agency serves as a link to greater nutritional knowledge for the public. It is your purpose to provide accurate information about food irradiation to the industry, media, and families of the United States.

Thank you for your time. I hope the FDA decides to uphold current laws regarding strict labeling and decides against weakening food labels. Please feel free to contact me if you have any questions.

RUSH HOLT

- Carrier 1

Member of Congress

SM/jp

No. 99-4989

Priya Narasimhan 6 Summit Trail Flemington, NJ 08822 priyan@mit.edu 3 58203

July 1, 1999

Congressman Rush Holt District office 50 Washington Road Princeton Junction, NJ 08550



Dear Congressman Holt:

Enclosed is a letter I sent to the FDA regarding the proposed changes in the labelling of irradiated foods. In light of the fact that irradiated foods have met with little success in the marketplace, the FDA is considering weakening labelling regulations so that irradiated foods would generate less alarm, thereby boosting their sales. Current regulations require irradiated whole foods to be prominently labelled with the term "irradiated." (or a related word) adjacent to the internationally recognized radura logo; irradiated ingredients in foods which are not themselves irradiated currently require no special labelling. Regarding whole foods, the FDA is considering eliminating the radura logo, reducing the size of the label or allowing a less prominent display, allowing misleading terms like "cold pasteurized" to replace "irradiated," and eliminating the labelling requirement altogether.

I strongly believe that consumers have a right to know whether their food has been irradiated. Numerous studies show that irradiated foods materially and substantially differ from non-irradiated foods, in terms of altered texture, taste and odor, vitamin loss, and potentially harmful radiolytic products. No long-term human feeding studies have been conducted on irradiated foods; animal studies show increased tumors, reproductive failures, and kidney damage. For the above reasons, I oppose the changes in labelling proposed by the FDA and am outraged by the move to disguise irradiated foods by eliminating or weakening labelling requirements.

Purthermore, I am appalled by the current regulations on foods with irradiated ingredients. Foods containing irradiated ingredients also suffer the vitamin losses caused by irradiation, and they contain the radiolytic products and free radicals that may be found in irradiated ingredients. Labelling of foods containing irradiated ingredients is necessary to ensure consumers' rights to make informed choices about their food.

As a concerned citizen and a member of your constituency, I urge you to support your constituents' right to information about their food. According to a 1997 nationwide poll, 77% of US consumers do not want irradiated food; it is completely unethical to impose irradiated food on citizens who don't want it, by denying them to right to information in the marketplace. Please urge the FDA to both maintain its labelling requirements of irradiated

98N-1038

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whole foods and strengthen its labelling requirements on foods with irradiated ingredients.

Thank you for your time.

Yours truly,

Priya Narasimhan